

technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Amendment for the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA) and section 1111 of the Public Health Service (PHS) Act, HHS is hereby giving notice that the charter for the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has been amended to set the time period for appointment of members to a term of up to 4 years. The effective date of the amendment is July 30, 2021.

FOR FURTHER INFORMATION CONTACT: Mia Morrison (DFO), Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301-443-2521; or mmorrison@hrsa.gov.

SUPPLEMENTARY INFORMATION: The ACHDNC provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning certain activities described in section 1111 of the PHS Act (42 U.S.C. 300b-10), as further described below. The ACHDNC is also governed by the provisions of the FACA, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The ACHDNC advises the Secretary of HHS about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having, or at risk for, heritable disorders. The ACHDNC will review and report regularly on newborn and childhood screening practices, recommend improvements in the national newborn and childhood screening programs, and fulfill responsibilities described in section

1111 of the PHS Act. In addition, the ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are considered evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the PHS Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

The filing date of the ACHDNC charter remains November 10, 2020. A copy of the ACHDNC charter is available on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is <http://www.facadatabase.gov/>.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: National Health Service Corps Scholar/Students To Service Travel Worksheet, OMB No. 0915-0278—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget

(OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 4, 2021.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: National Health Service Corps Scholar/Students to Service Travel Worksheet, OMB No. 0915-0278—Extension.

Abstract: Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program (SP) and the Students to Service (S2S) Loan Repayment Program (LRP) use the online Travel Request Worksheet to request and receive travel funds from the federal government to visit eligible NHSC sites to which they may be assigned in accordance with the Public Health Service Act, section 331(c)(1).

The travel approval process is initiated when an NHSC scholar or S2S participant notifies the NHSC of an impending interview at one or more NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has successfully been matched to an approved practice site in accordance with the Public Health Service Act, section 331(c)(3). Upon receipt of a completed Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the scholar or S2S participant and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

Need and Proposed Use of the Information: This information will facilitate NHSC scholar and S2S participants' receipt of federal travel funds that are used to visit high-need NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has

successfully been matched to an approved practice site.

Likely Respondents: Clinicians participating in the NHSC SP and the S2S LRP.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information

requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train

personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Travel Request Worksheet	300	2	600	.0667	40.02
Total	300	600	40.02

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to clarify and expand the authority for certain Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under section VI of this Declaration.

DATES: This amendment is effective as of August 4, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue

SW, Washington, DC 20201; 202-260-0365, paige.ezernack@hhs.gov.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving "willful misconduct" as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109-148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F-3, which addresses liability immunity, and section 319F-4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d-6e, respectively. Section 319F-3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113-5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the former Secretary, Alex M. Azar II, declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID-19 outbreak. Pursuant to section 319 of the PHS Act,

the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, January 21, 2021, April 21, 2021 and July 20, 2021.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID-19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID-19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary's Declaration and authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be